(15) (10)

Supreme Court, U.S.
FILED
MAR 18 1996
CLERK

Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC,
Petitioner/Cross-Respondent,

vs.

LORA LOHR AND MICHAEL LOHR,
Respondent/Cross-Petitioners.

On Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

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AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE CROSS-PETITIONERS

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BRIEF OF AMICUS CURIAE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE CROSS-PETITIONERS

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ["ATLA"] is a voluntary national bar association of approximately 50,000 attorneys who primarily represent plaintiffs in personal injury, civil rights, and commercial law cases. Letters of consent of the parties have been filed with the Court.

ATLA views the increasing willingness of some federal courts to find preemption of common law tort remedies as an assault on the fundamental right of injured persons to legal redress. Elimination of product liability claims as preempted by the Medical Device Amendments of 1976 represents a

particularly egregious violation of this right because Congress clearly did not intend this result.

SUMMARY OF ARGUMENT

1. Preemption under the MDA of state liability law depends entirely upon the proposition that by expressly preempting state "requirements," Congress clearly intended to include both administrative regulations and products liability actions. In fact, regulation and tort liability have long been understood as fundamentally distinct means of promoting product safety. Indeed, they may be understood as polar opposites with respect to the feature of greatest importance to preemption -- the use of government power.

While administrative regulation operates by direct governmental mandates, product liability affects product safety by indirectly influencing marketplace incentives. By making the manufacturer of an unreasonably dangerous product responsible for the harm it causes, products liability encourages manufacturers to undertake cost-effective safety measures.

This Court's decisions have long recognized that federal preemption of direct government regulation by states does not necessarily include the indirect effect exerted by liability law. It is unlikely that Congress intended a radical departure from these settled principles.

2. This Court has consistently instructed that courts may not find preemption of state tort remedies in the absence of clear and unambiguous evidence that Congress so intended. The presumption is particularly strong against preemption of traditional state tort law where injured persons would be left without any remedy. The lower court, while reciting the formula of presumption, did not accord it the appropriate weight.

The presumption against preemption is not merely a rule of statutory construction. It is essential to safeguarding the role of the states in the federal system. The responsibility of

courts to require a clear statement of Congressional intent to preempt state law minimizes intrusions on state autonomy safeguarded in the Tenth Amendment by assuring that states are afforded the opportunity to influence federal law through representation in Congress.

The strong presumption against preemption where no alternative remedy is provided serves to avoid potential deprivation of substantive due process.

3. The term "requirement" in §360k(a) does not clearly and unambiguously include product liability law. For that reason alone, the Court should decline to find preemption.

The plain text of the statute indicates that Congress intended to preempt state positive law, not product liability actions.

Medtronic identifies product liability verdicts as the offending state "requirement" within §360k(a). However, a verdict for plaintiff in a products case requires only that the defendant pay compensation to the injured plaintiff. It does not require the defendant to take any action with respect to the product. The role of the jury is to find facts; verdicts do not "establish" a legal requirement. Nor is the jury, particularly the jury in a federal diversity case, a "state."

Nor does this Court's decision in *Cipollone* support preemption under the MDA. The central teaching of *Cipollone* is that the scope of an express preemption provision is governed by the language of the specific statute. *Cipollone* explicitly recognizes that preemption of state "requirements" does not necessarily eliminate state tort actions for damages. In addition, this Court's decision in *Garmon* does not address the crucial distinction in this case between direct governmental regulation and the indirect influence of tort awards.

4. The legislative history of the MDA confirms that Congress intended to preempt only positive state law. Congress was acutely aware of product liability lawsuits against device

manufacturers. If it intended to eliminate such actions, it would have done so explicitly.

5. The interpretation of the FDA as to the scope of preemption under the MDA is to be accorded substantial deference. The FDA has consistently maintained that §360k(a) does not eliminate product liability actions.

ARGUMENT

Amicus addresses this Court on a single dispositive issue in this case: Whether a product liability verdict is a state "requirement" expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C.A. §§ 360c-360l (West Supp. 1994) [hereinafter "MDA"]. For nearly two decades after Congress enacted the MDA to protect consumers from unsafe medical devices, people injured by defective medical devices were afforded legal remedy. At the same time, Congress repeatedly rejected "tort reform" proposals to limit the liability of manufacturers whose products comply with FDA regulations. Recently, a majority of federal courts of appeals have "discovered" Congress intended to eliminate product liability actions. Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 941 (1994).

This dramatic reversal proceeds from a single proposition. The lower court, agreeing with the majority of U.S. courts of appeal, held that not only both positive law -- legislative and administrative regulation -- but also "common law actions are state requirements within the meaning of § 360k(a)." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 & n,7 (11th Cir. 1995); *contra Kennedy v Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995). This is also the basis for Medtronic's preemption argument to this Court. Brief For Petitioner Medtronic, Inc. ["Medtronic Brief"] at 37.

ATLA suggests that imputing this intent to Congress fails to recognize the fundamental distinction between administrative regulation and tort liability, fails to accord the

proper weight to the presumption against preemption, and misapplies this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). In addition, this interpretation conflicts with both the legislative history of the MDA and the Food and Drug Administration's own authoritative interpretation.

I. TORT LIABILITY AND ADMINISTRATIVE REGULATION ARE RADICALLY DIFFERENT SAFEGUARDS OF PRODUCT SAFETY

A. Tort Liability Creates Market Incentives for Safety, While Regulation Relies on Direct Governmental Mandates.

Medtronic appears to view state positive law and common law as Siamese twins -- sufficiently equivalent methods of regulation that Congress would naturally intend to include both within the term "requirement." Medtronic Brief at 36-40. Similarly, Medtronic attributes to Congress a willingness to eliminate common-law remedies, relying on federal regulation as the sole safeguard against dangerous medical devices. *Id.* at 47-48. ATLA suggests that this presumed equivalence between regulation and common law is a radical departure from longstanding principles of product safety in this country.

The vast array of products, their complexity, and mass production and marketing have dramatically increased the potential for harm to consumers. Much of the thrust of product safety law in this century has been aimed at assuring products are reasonably safe when they enter the marketplace. Indeed, it was the primary goal of Congress in enacting the MDA to vest the FDA with authority to conduct premarket analysis of medical devices similar to the regime applied to drugs. For a detailed history of device regulation, see Gail H. Javitt, *I've Got You Under My Skin-And I Can't Get Redress: An Analysis Of Recent Case Law Addressing Preemption Of*

Manufacturer Liability For Class III Medical Devices, 49 Food & Drug L.J. 553 (1994).

Administrative regulation differs from liability in so many areas that they are often viewed as polar opposites. *See* American Law Institute, Reporters' Study: Enterprise Responsibility For Personal Injury vol I, 47-49 (1991); Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 12 J. Prod. Liab. 305 (1989); Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Studies 357 (1984). Of greatest importance for purposes of preemption analysis is the crucial difference in their use of the power of government.

State product liability law, in addition to providing compensation to wrongfully injured persons, also seeks to assure reasonable safety in products that enter the marketplace. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825 (1973). In his classic exposition, Judge Calabresi, contrasts governmental regulatory mandates, which he labels "specific deterrence," with the indirect influence of "general deterrence" exerted by tort law. Guido Calabresi, The Costs of Accidents 68-129 (1970).

Products liability is premised on the idea that the cost of harm caused by an unreasonably dangerous product should be borne by those who have placed it in the stream of commerce, who can spread those costs through the purchase price. Restatement (Second) of Torts §402A, comment c (1965). In the absence of liability, those costs fall on the injured consumer, who may be covered by insurance or government programs. Nonliability is, in effect, a subsidy to the makers of unsafe products, giving them an economic advantage over producers who have invested in safety. Calibresi, *supra*, at 70. Product liability forces manufacturers to "internalize" the cost of harm caused by unreasonably dangerous products, so that the purchase price of a product reflects its true social cost. The manufacturer can then determine the most cost-efficient

means of minimizing those costs. Where prevention of injury is cheaper than compensating the victims, the manufacturer will invest in safety. *See* William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 Yale L.J. 1099, 1119-20 (1960); Richard C. Ausness, *Compensation For Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 46 Wayne L. Rev. 1085, 1140 (1990)("efficient allocation of resources is more likely if product prices reflect their actual social costs, including the cost of product injuries that are economically or technologically unavoidable.").

Regulation, on the other hand, trumps private decisionmaking. As one scholar summarized:

> [U]nder a general deterrence regime, manufacturers, not government officials, make decisions about product safety. . . . In contrast, specific deterrence mandates a particular choice determined by the legislature or an administrative agency. *It is a raw exercise of state power* . . .

Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 Syracuse L. Rev. 897, 927 (1988)(emphasis added).

In view of this fundamental distinction, amicus suggests that tort liability inherently poses far less of a danger of conflict with federal regulatory efforts than state administrative requirements. It is improbable that Congress would view express preemption of state "requirements" as necessarily including both tort liability and state administrative regulation.

B. This Court Has Consistently Held That Preemption Of State Regulation Does Not Necessarily Include The Indirect Effects Of Tort Liability.

This Court's preemption decisions have long recognized the distinction between the indirect effect of tort liability on

private decisionmakers and direct government regulation. In *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984), the Court found no inconsistency between "vest[ing] the NRC with exclusive regulatory authority over the safety aspects of nuclear development while at the same time allowing plaintiffs like Mr. Silkwood to recover for injuries caused by nuclear hazards." Indeed, both dissenting opinions agreed with the majority that, with respect to compensatory damages, preemption of state administrative regulation does not necessarily entail preemption of state tort remedies:

> Whatever compensation standard a State imposes, whether it be negligence or strict liability, a licensee remains free to continue operating under federal standards and to pay for the injury that results. . . . Compensatory damages therefore *complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme*.

Id. at 264 (Blackmun, J., dissenting)(emphasis added). Justice Powell's view was that, [t]here is no element of regulation when compensatory damages are awarded, especially when liability is imposed without fault, as authorized by state law. *Id.* at 276 n.3.

Relying on *Silkwood*, the Court later explained that:

> The effects of *direct* regulation on the operation of federal projects are significantly more intrusive than the *incidental* regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award if an employee's injury is caused by a safety violation. We believe Congress may reasonably determine that *incidental regulatory pressure is acceptable, whereas direct regulatory authority is not*.

Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 185 (1988)(emphasis added). Shortly thereafter, the Court reaffirmed the importance of this distinction:

> [F]or a state law to fall within the pre-empted zone, it must have some direct and substantial effect on the decisions made by those who build or operate nuclear facilities concerning radiological safety levels. We recognize that a claim for intentional infliction of emotional distress at issue here may have some effect on these decisions, because liability for claims like petitioner's will attach additional consequences to retaliatory conduct by employers. As employers find retaliation more costly, they will be forced to deal with complaints by whistleblowers by other means, including altering radiological safety policies. Nevertheless, we believe that this effect is neither direct nor substantial enough to place petitioner's claim in the preempted field.
>
> This result is strongly suggested by the decision in *Silkwood v. Kerr-McGee Corp.*

English v. General Electric Co., 110 S. Ct. 2270, 2278 (1990).

As Justice Blackmun later described the import of these decisions, "The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory impact of the common law from positive enactments such as statutes and administrative regulations." *Cipollone*, *supra*, at 112 S. Ct. at 2628, 505 U.S. 536-37 (Blackmun, J., concurring in part, dissenting in part).

This distinction underlies the Court's approach to preemption under ERISA. In *Pilot Life Ins. Co. v. Dedeaux*, 107 S. Ct. 1549, 1554 (1987), the Court concluded that tort law is not a state law which "regulates" insurance, stating that a "common-sense view of the word 'regulates' would lead to the conclusion that in order to regulate insurance, a law must

not just have an impact on the insurance industry, but be specifically directed toward that industry".

The Court employed a similar analysis in *New York v. United States*, 112 S. Ct. 2408 (1992), finding that financial incentives to encourage states to enforce federal radioactive waste policy did not intrude upon state sovereignty protected by the Tenth Amendment. But "directly compelling them to enact and enforce a federal regulatory program" did. *Id.* at 2420.

II. COURTS MAY NOT FIND PREEMPTION OF STATE TORT REMEDIES UNLESS CONGRESS HAS CLEARLY AND UNAMBIGUOUSLY SO INTENDED.

A. Preemption of State Judicial Remedies Must Be Established by Clear and Unambiguous Statement of Congressional Intent to Protect State Sovereignty Guaranteed by the Tenth Amendment.

1. Regard for federalism requires a strong presumption against preemption of state tort law in the absence of clear and unambiguous Congressional intent.

Although the lower court recited the well-settled principle that there is a strong presumption against preemption of state tort remedies, Amicus submits that the evidence of congressional intent to eliminate product liability actions falls far short of what is necessary to overcome this presumption.

Recognizing that "the regulation of health and safety matters is primarily and historically a matter of local concern," *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 719 (1985), the Court has instructed that there is a strong "basic assumption that congress did not intend to displace state tort law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Milwaukee v. Illinois*, 451 U.S. 304, 316 (1981). This Court has consistently adhered to the principle:

> [When Congress legislates] in a field which the States have traditionally occupied . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). This principle applies to the interpretation of express preemption provisions. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2617 (1992), quoting *Rice*.

This presumption is not merely a rule of construction; it is an obligation of the judicial branch essential to avoid "unintended encroachments on the authority of the States." *CSX Transp. Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993).

Thus, "the ordinary rule of statutory construction [is] that if Congress intends to alter the 'usual constitutional balance between the States and the Federal Government,' it must make its intention to do so 'unmistakably clear in the language of the statute.'" *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 62 (1989), quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985).

2. Preemption of state tort remedies is an intrusion upon fundamental rights historically safeguarded by the states.

The strong presumption against preemption of state law is even stronger where preemption would leave injured persons without legal redress. Affording remedy for inury is a principal responsibility of government

> To take from an injured person all such remedies, without any replacement, threatens the very foundation of our legal system: "[T]he refusal to redress an otherwise actionable wrong creates disrespect for the law and encourages the victim to take matters into his own hands."

Carlisle v. Philip Morris, Inc., 805 S.W.2d 498, 512 (Tex. App. 1991), quoting *Lynn v. United Plant Guard Workers*, 383 U.S. 53, 64 (1966). The right to a remedy is expressly guaranteed by thirty-seven state constitutions. Francis E. McGovern, *The Variety, Policy and Constitutionality of Product Liability Statutes of Repose*, 30 Am. U.L. Rev. 579, 615 n.218 (1981); Note, *Constitutional Guarantees of a Certain Remedy*, 49 Iowa L. Rev. 1202 (1964).

The continued vitality of state constitutional protections of tort remedies is reflected in the decisions of state supreme courts striking down state legislation which limits recoverable damages. *See, e.g., Moore v. Mobile Infirmary Assoc.*, 592 So. 2d 156 (Ala 1991); *Smith v. Department of Insurance*, 507 So. 2d 1080 (Fla. 1987); *Kansas Malpractice Victims Coalition v. Bell*, 757 P.2d 251 (Kan. 1988); *Lucas v. United States*, 757 S.W.2d 686 (Tex. 1988); *Sofie v. Fibreboard Corp.*, 771 P.2d 711 (Wash. 1989).

3. Requiring Congress to speak plainly when preempting state law protects state sovereignty.

The Court gave substantive content to the Tenth Amendment[1] in *National League of Cities v. Usery*, 426 U.S. 833 (1976), holding Congress may not exercise power in a fashion that impairs the States' "traditional government functions" *Id.* at 854-55.

When the Court overruled *National League of Cities* a decade later in *Garcia v. San Antonio Metropolitan Transit Authority*. 469 U.S. 528 (1985), the Court did not devalue federalism, but concluded that it is "more properly protected by the procedural safeguards inherent in the structure of the federal system," through the states' representation in Congress. *Id.* at 552. This safeguard can be effective only

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[1]The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.
U.S. Const., amend. X.

when courts require clear and unambiguous evidence that Congress indeed intended preemption. As Justice O'Connor has explained:

> By declining to infer preemption in the face of congressional ambiguity, the Court is . . . requiring that decisions restricting state sovereignty be made in a deliberate manner by Congress . . .
>
> Application of the plain statement rule thus may avoid a potential constitutional problem. Indeed, inasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise.

Gregory v. Ashcroft, 111 S. Ct. 2395, 2403 (1991).[2]

The strong presumption against preemption thus safeguards state autonomy. Laurence H. Tribe, American Constitutional Law § 6-25, at 479-80 (2d ed. 1988), quoted in *Gregory supra;* Barbara A. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 Buff. L. Rev. 181, 182 (1991); Paul Wolfson, *Preemption and Federalism: The Missing Link*, 16 Hastings Const. L.Q. 69, 112 (1988)("The

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[2]State courts exhibit greater sensitivity than their federal counterparts to the incursions on state autonomy resulting from broad judicial declarations of preemption not supported by clearly and unambiguously articulated congressional intent:

> . . . if the common law claims of two hundred years are to be curtailed, if the courts of the States are to be deprived of deciding the cases that have been their historial province, if the supremacy clause is to mean preemption *uber alles*, then let the execution of the tort system be public. Let the sword of supremacy be wielded by congress in the full light of day . . .

Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 215 (Ill. App. 1994).

courts can, however, simultaneously protect the political safeguards of federalism and afford the necessary deference to Congress by requiring that Congress speak clearly and explicitly whenever it preempts state legislation.")

Judge Kenneth Starr has observed that the Court's increasing insistence upon a clear statement of congressional intent as a basis for preemption fosters a healthy federalism and accountability on the part of Congress. Kenneth Starr, et al., The Law of Preemption: A Report of the Appellate Judges Conference of the American Bar Association 40 & 50-55 (1991). It also preserves the proper role of the judicial branch, since "[w]hen judges preempt state laws in the absence of explicit congressional guidance, they in effect assume a legislative role without accepting legislative responsibility." *Id.* at 48.

B. Abolition of Common Law Remedies Without Alternative Means For Redress Is Constitutionally Suspect.

The presumption against preemption is even stronger where, as here, federal preemption of state law remedies provides no alternative means of redress. *See United Construction Workers v. Laburnum Const. Co.*, 347 U.S. 656, 663-64 (1954). As the Court explained in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984):

> This silence [of Congress] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

464 U.S at 251. Justice Blackmun, dissenting in *Silkwood*, was equally emphatic on this point: "The absence of federal regulation governing the compensation of victims is strong evidence that Congress intended the matter to be left to the States." *Id.* at 264 n.7. *See also, Abbot v. American*

Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir. 1988)("The presumption is even stronger against preemption of state remedies, like tort recoveries, when no federal remedies exist.").

Amicus suggests that this is not merely a rule of construction. The common-law right to seek redress in the courts for wrongful injury holds a special place in our civil justice system. Indeed, they preceded even the Constitution. Lord Coke traced this right to the Magna Carta.[3] Chief Justice Marshall stated that

> the very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection.

Marbury v. Madison, 5 U.S. (1 Cranch) 137, 163 (1803). This right of access to justice is so fundamental that this Court has located "the duty of every State to provide, in the administration of justice, for the redress of private wrongs" in the Due Process Clause of the Fourteenth Amendment. *Missouri Pacific Ry. Co. v. Humes*, 115 U.S. 512, 521 (1885).

Indeed, the Court has suggested that the federal government's elimination of a state tort law remedy without providing some alternative recourse may violate substantive due process. In *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59 (1978), the Court suggested that abolition of the common law right to a tort remedy in the Price-Anderson Act might violate due process but for the "panoply of remedies and guarantees" provided by Congress. *Id.* at 86-88 and 91-93. Justice Marshall later remarked that "our cases demonstrate that there are limits on governmental

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3 Every Subject may take his remedy by the course of the Law, and have justice, and right for the injury done to him, freely without sale, fully without denial, and speedily without delay.
Coke, Second Institute 55-56 (4th ed. 1671).

authority to abolish "core" common-law rights, . . . at least without a compelling showing of necessity or a provision for a reasonable alternative remedy." *PruneYard Shopping Center v. Robins*, 447 U.S. 74, 93-94 (1980)(Marshall, J., concurring).

Amicus submits that, while the lower court recited the formula of the presumption, 56 F.3d at 1341, the express preemption provision does not approach the clear and unambiguous expression necessary to overcome this presumption.

III. THE PLAIN TEXT OF THE MDA DOES NOT REFLECT A CLEAR AND MANIFEST INTENT TO PREEMPT STATE TORT LAW.

Cipollone's primary directive to federal courts is that the preemptive scope of a federal statute "is governed entirely by the express language." 112 S. Ct. at 2618. Section 360k(a) of the MDA provides:

> (a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement---
>
> (1) which is different from or in addition to, any requirement applicable under this Act to a device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

A. The Term "Requirement" Does Not Clearly And Unambiguously Include Product Liability.

In view of the sharp differences between regulation and liability actions, it is clear that the term "requirement" does not always, or even usually, refer to both. In *Cipollone*, this Court emphasized "there is no general, inherent conflict between federal preemption of state warning *requirements* and the continued vitality of state common law damages

actions." 112 S. Ct. at 2618 (emphasis added). Thus, even if a court may devise an interpretation of "requirement" that includes tort actions, it can, at best, suggest that the term is ambiguous. The lower court acknowledged that "Congress' choice of the word 'requirement' in §360k(a)(1), does not speak directly to the precise issue of whether Appellants' state common law tort claims are preempted by the MDA. As used in §360k(a), a 'requirement' refers to a legal obligation, . . . Even using this ordinary meaning, the scope of the word 'requirement' is ambiguous . . ." 56 F.3d at 1344.

Amicus suggests that in the face of such ambiguity, the strong presumption against preemption mandates that the court preserve the state law claims and reject preemption. As Justice Scalia observed, *Cipollone* requires that when a statute expressly preempts state law, "it must do so with great exactitude, as any ambiguity concerning its scope with be read in favor of preserving state power." 112 S. Ct. at 2634 (Scalia, J., dissenting). *See also Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2245 (1994)("But even accepting that §151a is susceptible of more than one interpretation, no proposed interpretation demonstrates a clear and manifest congressional purpose" to preempt state law).

B. The Plain Meaning Of The MDA Reflects Congressional Intent To Preempt State Administrative Regulation, Not Product Liability Actions.

1. The text of §360k(a) indicates that congress intended requirement to include only positive law.

The text of §360k(a) clearly indicates that Congress intended to preempt only legislative or administrative regulation. Congress uses the term "requirement" three times in this section. Two instances refer to a "requirement . . . under this Act," clearly a legislative or administrative requirement. Usage of the identical term, without further qualification or comment, to refer to preempted state law

suggests that Congress had in mind state legislative or administrative regulation."

2. A jury verdict does not establish a "requirement" with respect to a device.

It is important to ascertain precisely what is the offending state "requirement." The lower court indicated that it is the jury verdict in a products liability case that violates. §360k(a). 56 F.3d at 1343 ("it is for [the agency], not a jury . . ."). [4] Medtronic unequivocably asserts that it views the liability verdict as a "requirement." Medtronic Brief at 40 ("requirement . . . would be established by Florida state judges and juries"); and at 44 ("if plaintiffs' claims succeed" they would impose different or additional "requirements").

Indeed, nearly every court finding preemption under the MDA has viewed jury awards as establishing a state requirement.[5] *See Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 751 (M.D. Pa. 1992), *aff'd*, 5 F.3d 1489 (3d Cir. 1993)("A jury's finding of liability effectively creates a new standard or duty which defendants must follow."); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404, 407 (E.D. Mich. 1987)(A jury award "effectively compels the manufacturer to alter its warning to conform to different state law

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[4]The lower court frequently refers to preemption of plaintiff's "claims" or "action." Since the Supremacy Clause provides for preemption only of state "law," this is not literally correct. It is reasonable to assume that the court refers to dismissal of claims because "if successful" the verdict would establish a requirement. *See King*, 983 F.2d at 1155, quoted in the text.

[5]*Cipollone* focused on generally applicable "legal duties" imposed by common law. 505 U.S. at 522. Section 360k(a), however, is narrower in scope, preempting only requirements "with respect to a device." General duties to exercise due care, to refrain from marketing unreasonably dangerous products, and to conform to warranties are not requirements "with respect to a device." They are requirements with respect to the conduct of product suppliers. Moreover, §360k(a) is limited to a requirement which "relates to the safety or effectiveness of *the* device." (emphasis added) General tort duties relate to all devices -- indeed, to all products.

requirements as 'promulgated' by the jury's findings.); *Covey v. Surgidev Corp.*, 815 F.Supp. 1089, 1094 (N.D. Ohio 1993)(great majority of courts have "reached the conclusion that a jury verdict in a tort suit under state law is a requirement" under the MDA). *See also King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993); *Stamps*, 984 F.2d at 1421; *Reeves v. Acromed Corp.*, 44 F.3d 300, 305 & 306 (5th Cir. 1995)(jury finding "tantamount to imposing a requirement").

This argument fundamentally misunderstands the role of the jury (or judge in a bench trial). The Supremacy Clause establishes preemption of state law. Jury's role, however, is to make findings of fact, not law. Medtronic's argument rests entirely on the notion that jury verdicts establish tort duties. The fact is that it is the breach of duty that gives rise to the jury verdict.

The fact is, a jury verdict in a product case "requires" only that the defendant pay compensation to the plaintiff. The court in *King v. Collagen Corp.* argued that: "If successful, the claim would require Collagen to redesign Zyderm, remove it from the market, or be subject to strict liability." 983 F.2d at 1135. However, this is precisely the range of options open at all times to any manufacturer whose product causes injury.

The jury's verdict imposes no legal obligation with respect to the product involved. Modifying the product does not preclude a subsequent plaintiff from establishing that it is unreasonably dangerous.[6] Nor does the manufacturer's decision not to make such a modification result in any legal consequence. A subsequent plaintiff must satisfy the same tort elements as the previous plaintiff. In short, the defendant retains the option of choosing between taking steps to prevent

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[6]As a practical matter, it would be difficult to identify what action the jury's verdict might "require." Generally, a jury is asked to find whether the product is unreasonably dangerous; it does not determine what design or warning would be reasonably safe.

future harm or compensating future injured claimants. *See Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1540-41 (D.C. Cir. 1984); *Burke v. Dow Chemical Co.*, 797 F. Supp. 1128, 1138 (E.D.N.Y. 1992)(noting that *Ferebee* "remains a leading case"). In fact, a significant number of manufacturers who have been sued make the choice not to modify the product or warnings.[7]

It is true that the prospect of possible damage awards creates an incentive for the company to avoid future liability by improving the safety of its product. However, "[i]mposing a burden on the sale in the form of potential liability for defective design is distinguishable from a state seeking to exert actual control over the mode of manufacture or distribution of a specific product." *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743, 745 (D.N.M. 1987); Philip H. Corboy and Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 Am. J. Trial Adv. 435, 452-57 (1992). *Compare, New York Conference of Blue Cross v. Travelers Ins.*, 115 S. Ct. 1671 (1995)(not every regulation that affects cost of insurance "relates" to benefit plans).

3. Product liability awards do not constitute a requirement established by the State.

A jury is not, a "State or political subdivision." Moreover, in ordinary parlance, a state does not "establish" or "continue" a jury verdict. Although a jury award is "only enforceable under state law" by entry of judgment by a court, it is not "imposed by the state." *Cipollone*, 112 S. Ct. at 2622 n.24.

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[7]E. Patrick McGuire, The Impact of Product Liability 18 (Conference Bd. 1988)("Nearly half of the companies with actual product liability experience . . . have improved their product use and warning materials. And a third say that they have redesigned their product lines to improve safety.")(context suggests substantial overlap of these two groups).

In this case, Medtronic's argument would lead to the ludicrous result that a federal jury sitting in a diversity case in federal district court would constitute a "State or political subdivision" within the meaning of the Act.

4. 360k(b) indicates that Congress intended to preempt only positive law.

Section § 360k(b), which authorizes the Secretary to exempt state requirements that are more stringent than FDA requirements or are compelled by local conditions, is clearly addressed to administrative regulation. One court has suggested application to damage awards would lead to "absurd" results. *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989). As two scholars have stated, §360k(b):

> is entirely inconsistent with an intent to have the term 'requirement' include the common law. . . . Clearly, Congress intended for this subsection to apply only to legislative type enactments by the states and not to common law tort claims.

Adler and Mann, *supra*, at 927-28 .

5. Section 360h(d) Reflects Congressional Intent To Preserve State Tort Actions

If Congress had intended to eliminate tort lawsuits, it would have employed language specifically denoting tort actions or common law actions. "Congress has long demonstrated an aptitude for expressly barring common law actions when it so desires." *Taylor v. General Motors Corp.*, 875 F.2d 816, 824 (11th Cir. 1989). *Pappas v. Upjohn Co.*, 926 F.2d 1019, 1023-24 (11th Cir. 1991)(same); *Worm v. American Cyanamid Co.*, 970 F.2d 1301, 1305 (4th Cir. 1993)("Congress has not failed to make such preemption clear when it desires to do so.").

Indeed, Congress employed very specific language in another section of the MDA when it intended to preserve

common law liability. 21 U.S.C. §360h provides that a "device . . . that presents an unreasonable risk of substantial harm to the public health" may be subject to an order by the Secretary requiring the repair, replacement, refund, or recall of the device. Congress then explicitly states:

> Compliance with an order issued under this section *shall not relieve any person from liability* under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360h(d)(emphasis added).

This provision clearly reveals that Congress anticipated liability actions under state law would continue under the MDA. *See Mulligan v. Pfizer, Inc.*, 1994 WL 158819 (S.D. Ohio, April 1, 1994)(§360h(d) "specifically contemplates state law liability and damages"); *Truxillo v. Ray-Ban, Div. of Bausch & Lomb, Inc.*, 1992 WL 209302 (E.D. La., Aug. 11, 1992). If Congress had intended to include damage awards within the preemptive scope of §360k(a), it would have used equally clear and specific language. Adler and Mann, *supra*, at 929.

C. The Court's Decision in *Cipollone* Does Not Require that State Court Remedies Be Preempted Under the MDA.

1. Cipollone decision does not define "requirement" to include tort jury verdicts.

Medtronic relies heavily on what it construes as this Court's holding in *Cipollone* "applies directly to this case." Brief at 39.

Medtronic's attempt to import the Court's interpretation of "requirement" into a wholly unrelated statute flies in the face of *Cipollone's* central teaching, that the scope of express

preemption depends upon the text of the specific statute. 112 S. Ct. at 2618.

The text construed in *Cipollone* included the phrase "or prohibition." The Court found that some common law causes of action were preempted by the Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87, which provided in §5 "No *requirement or prohibition* based on smoking and health shall be imposed under State law." On the other hand, the 1965 Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §1334, which provided "No statement relating to smoking and health . . . shall be *required*" (emphasis added) preempted state legislative and administrative regulation, but not state law damage actions. *Id.* at 2619. In view of the plurality's statement that there is "no general, inherent conflict between federal preemption of state warning *requirements* and the continued vitality of state common law damages actions," 112 S. Ct. at 2618 (emphasis added), it seems clear that the Court viewed the words "or prohibition" as significant in expanding the preemptive scope to include tort actions. To the extent that *Cipollone's* definition of "requirement" is at all applicable to the MDA, it supports Amicus' argument that the term "requirement" does not itself necessarily encompass product liability actions.

2. Garmon does not support preemption.

Medtronic also relies on a statement in *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959), that state "regulation can be as effectively asserted through an award of damages as through some form of preventive relief." Brief at 37.

In that case, however, it was not necessary for the Court to distinguish between the incidental effects of tort law and direct regulation. Rather, the statutory scheme in that case deprived state courts of jurisdiction entirely.

In *Garmon*, an employer won damages in a tort action in California state court against a labor union that had picketed

plaintiff's lumber business. Reversing, the Supreme Court ruled that with respect to such activities, "the States as well as the federal courts must defer to the exclusive competence of the National Labor Relations Board." *Id.* at 245. As this Court later explained, *Garmon* was chiefly concerned with "ensuring that the primary responsibility for interpreting and applying this body of law remained with the NLRB. . . based on the primary jurisdiction rationale." *Brown v. Hotel & Restaurant Employees & Bartenders International Union Local 54*, 468 U.S. 491, 502 (1984). *See also English v. General Electric Co.*, 496 U.S. 72, 86-87 n.8 (1990).

It is also significant that the *Garmon* Court carefully conditioned its ouster of state law on the understanding that access to justice would be assured through alternative federal remedies. The majority opinion emphasized the fact that NLRA established a set of procedures and remedies in place of the state law remedies displaced by the Act. 359 U.S. at 243. The concurring justices cautioned that, where Congress has not provided a remedy for tortious conduct, "there is no ground for concluding that existing criminal penalties or liabilities for tortious conduct have been eliminated." *Id.* at 252 (Harlan, J., concurring), quoting *United Construction Workers v. Laburnum Const. Co.*, 347 U.S. 656, 665 (1954).

IV. THE LEGISLATIVE BACKGROUND OF MDA DOES NOT INDICATE CONGRESSIONAL INTENT TO PREEMPT PRODUCT LIABILITY ACTIONS.

In *Cipollone*, the Court held that the 1965 Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §1334, did not preempt state law damage actions. 112 S. Ct. at 2619. The Court based its interpretation on the express language of the statute "[r]ead against the backdrop of regulatory activity undertaken by state legislatures and federal agencies" which "were the catalyst for passage of the 1965 Act." *Id.* It is therefore appropriate to examine the MDA's "legislative context."*Id* at n.16.

A. Congress Intended To Make Regulation Of Devices More Consistent With Regulation Of Drugs Under The Parent Statute, Which Does Not Preempt Tort Law.

Congress did not enact the MDA in a vacuum. The amendments were intended to remedy deficiencies in the Federal Food Drug and Cosmetic Act of 1938, 21 U.S.C. §§321-92 It is well-settled that regulations under the FDCA do not preempt state tort causes of action. *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1176-77 (5th Cir. 1988); *Abbott v. American Cyanamid Co.*, 844 F.2d 1108, 1112 & n.1 (4th Cir.), cert. denied, 488 US 908 (1988). Indeed Congress explicitly rejected a proposed "right of action for damages" for violation of the Act as unnecessary because plaintiffs would continue to have a common law cause of action. Hearings on S. 1944 Before a Subcommittee of the Committee on Commerce, U.S. Senate, 73rd Cong., 2d Sess. 400 (1933). *See Consumer Federation of America v. Upjohn*, 346 A.2d 725, 731 (D.C. App. 1975)(citing legislative history). Congress could reasonably have understood that product liability actions would continue under the 1976 amendments to that statute.

Additionally, one goal of the MDA was the elimination of definitional disputes between FDA and manufacturers as to whether a product would be classified as a drug or as a far less regulated device. Gail H. Javitt, *supra*, at 566-68. It would be anomalous for Congress to perpetuate this problem by bestowing immunity from tort liability only upon device manufacturers.

B. If Congress Intended To Eliminate Products Liability, It Would Have Done So Explicitly.

The catalyst that resulted in passage of the MDA was the Dalkon Shield scandal. "This contraceptive device, as well as heart valves and pacemakers, became the symbols that spurred Congressional action to protect the public from the harmful effects of a largely unregulated device industry."

Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1434 (C.D. Cal. 1994). *See also Michael v. Shiley, Inc.*, 46 F.3d 1316, 1319 (3rd Cir. 1995); *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 753 (S.D.N.Y. 1994). Witness after witness in congressional hearings decried the numerous injuries and deaths caused by this device. *See* S. Rep. No. 94-33, 94th Cong., 2d Sess. (1976), reprinted in 1976 U.S. Code & Admin. News 1070, 1071. Laura K. Jortberg, *Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments Under* Slater v. Optical Radiation Corp., 43 DePaul L. Rev. 963, 978 (1994).

Those injuries and deaths occasioned numerous lawsuits against the manufacturer, A.H. Robins Co., including a verdict for puntive damages. *Deemer v. A.H. Robins Co.*, No. C-30649 (Kan. Dist. Ct., Feb. 7, 1975). By 1976, Dalkon Shield lawsuits were the largest category of product liability actions pending in federal court, outnumbering by far even asbestos cases. U.S. General Accounting Office, Product Liability: Extent of "Litigation Explosion" in Federal Courts Questioned, HRD-88-36BR (Jan. 1988) at 22.

Congress was well aware of these lawsuits. "Presently, more than 500 lawsuits seeking compensatory and punitive damages totaling more than $400 million are pending against the manufacturer of the Shield.." H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976). Under those circumstances, ATLA suggests, it is inconceivable that Congress would have acted to eliminate such civil actions without significant debate. However, "careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Adler and Mann, *supra*, at 922 n.128.

C. Congress Intended § 360k(a) To Apply to State Administrative Regulation.

The lower court imputed to Congress "twin purposes" in enacting the MDA: Protection of the public, counterbalanced by avoidance of overregulation that might stifle progress.

Lohr, 56 F.3d at 1335. development. However, the exerpt from the House Report quoted by the court explicitly cautions against "excessive or ill-conceived *Federal* device regulation." *Id.*, quoting H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976). Congress made no reference to state product liability lawsuits. *See* Adler and Mann, *supra*.

The only discussion in the legislative history concerning the motivation behind §360k concerns state administrative regulation:

> In absence of effective Federal regulation of medical devices some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. . . . Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to premarket clearance in California.

House Rep. No. 853, 94th Cong., 2d Sess. at 45-46 (1976)(emphasis added).

This is precisely the type of "backdrop of regulatory activity undertaken by state legislatures" which convinced the *Cipollone* court that "no statement relating to smoking and health shall be required" included only positive law, not common law liability. 112 S. Ct. at 2619. *See also Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 754-55 (S.D.N.Y. 1994); *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667-68 (D. Md. 1989).

V. THE FDA DOES NOT INTERPRET THE MDA AS PREEMPTING PRODUCT LIABILITY ACTIONS.

The lower court properly relied on the FDA's interpretation of "requirement" under the MDA. 56 F.3d at 1344-45. However, the court failed to accord any weight to

the FDA's view that state "requirement" does not include product liability actions.

This Court has instructed that "the construction of a statute by those charged with its administration is entitled to substantial deference." *United States v. Rutherford*, 442 U.S. 544, 553 (1979). Indeed, the Court has deemed the FDA's interpretation of its own regulations "dispositive" on the issue of preemption of state law. *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S 707, 714 (1985).

21 C.F.R. 808.1(d)(1) provides:

> Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

Actions based on implied warranty of fitness without privity are substantially identical to strict liability actions. *See* Restatement (Second) of Torts § 402A (1965) comment *m*. Strict liability, as well as negligence, fraud, and misrepresentation, relate to all products in addition to devices. apply to product suppliers generally and are not limited to devices. The FDA clearly does not view product liability as preempted by §360k(a).

Several courts have discerned a contrary view in 21 C.F.R. §808.1(b), which declares that no state "may establish or continue in effect any requirement with the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*)(emphasis added). See *Stamps*, 984 F.2d at 1421 nn. 1 & 2. However, the FDA did not intend the term "court decision" to refer to common law causes of action for damages. Jury verdicts are not court decisions. Moreover, the

regulation subsequently makes it clear that it refers to court decisions interpreting positive law enactments:

> In determining whether such a [state] requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the state or local government and not the literal language of the *state statute* which may be identical to a provision in the act.

21 C.F.R. 808.1(d)(6)(ii)(emphasis added). As the FDA explained the regulation in connection with its promulgation as a final rule:

> When determining whether a State or local requirement is preempted, however, the Commissioner will consider how the requirement is interpreted and applied, not merely the literal language of the *applicable statute*.

43 Fed. Reg. 18663 (May 2, 1978)(emphasis supplied).

The agency has consistently adhered to its view that the MDA does not preempt product liability. 21 C.F.R. §808.5 authorizes the Commissioner to issue advisory opinions "concerning preemption of State or local device requirements." The advisory opinion "[r]epresents the formal position of the FDA" and is binding on the agency. 21 C.F.R. §10.85(e). In one such opinion, the Office of the Chief Counsel for the FDA stated:

> *There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies*, . . . Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

Advisory Opinion by Joseph P. Hile, Associate FDA Commissioner for Regulatory Affairs, Docket No. B3A-0140/AP, Mar. 2, 1984. *quoted in Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1435 (C.D. Cal. 1994); reprinted in Pet. App. 4a-6a.

The Chief of the Regulations Staff subsequently restated that this interpretation that "the FDA believes that Section 521 does not preempt general product liability requirements." Letter from Joseph Sheehan, Chief, Regulations Staff, Food and Drug Administration, to Cindy Whaley, Esq. (Feb. 2, 1987) reprinted at Pet. App. 7a

CONCLUSION

For these reasons, Amicus urges the Court to reverse the order of the lower court in this case.

Respectfully submitted,

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March 13, 1996